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November 8, 2024

**VIA ECF**

Hon. Brian M. Cogan  
United States District Court  
Eastern District of New York  
225 Cadman Plaza East  
Brooklyn, NY 11201

**Re: In re: Oral Phenylephrine Marketing and Sales Practices Litigation  
1:23-md-03089-BMC**

**FDA's Proposed Administrative Order**

Dear Judge Cogan:

On November 7, the FDA initiated a notice-and-comment period regarding a proposed administrative order amending the over-the-counter monograph for cold, cough, allergy, bronchodilator, and antiasthmatic drug products. The FDA's statement regarding its action is available here: <https://tinyurl.com/mr2tbh4r>. (Also attached as Ex. A.) The proposed order is available here: <https://tinyurl.com/5n8pes6j>.

The parties write to advise the Court of their view of the impact of the proposed order on the parties' pending joint motion requesting entry of judgment and cancellation of the November 21 hearing scheduled in this case. (ECF No. 250.)

**Plaintiffs' Position**

In light of the FDA announcement, Plaintiffs believe that entry of judgment should be held in abeyance until the parties can better assess this development and discuss its significance to the case (including as it relates to the Court's recent grant of Defendants' motion to dismiss), both internally and with each other.

Given that a status conference is scheduled for November 21, 2024, Plaintiffs respectfully request that that entry of judgment be held in abeyance and that deadlines related to any motion to reconsider also be extended until after that conference on November 21st, so that the parties have an opportunity to address this development and our views of its significance with the Court at that conference.

As always, we thank the Court for its attention to this case and we are, of course, available at your convenience before the November 21st conference if you so desire.

### **Defendants' Position**

The FDA's proposed order announcing a notice-and-comment rulemaking related to phenylephrine has no impact on this case and should not delay this Court from entering judgment as the parties jointly requested earlier this week. *See* ECF No. 250.

The FDA's statement accompanying the proposed order made clear that "[f]or now, companies may continue to market OTC monograph drug products containing oral phenylephrine as a nasal decongestant. This is a proposed order. Only a final order will affect what products can be marketed."<sup>1</sup> The Court even considered the impact of a future monograph change in its Order and held that any impact from such a change would be prospective-only. ECF No. 249. at 9 ("[U]nless and until the FDA amends the monograph in response to the NDAC's findings, it is not misleading to state that PE is an effective nasal decongestant."). The FDA's proposed order provides no basis to delay entering judgment.

While Defendants defer to the Court on whether it would like to proceed with the status conference, they do not believe there is any need to hold a status conference in order to discuss the parties' "views" on the impact of the proposed order to the Court's ruling. Defendants therefore respectfully request that this Court enter the proposed order entering judgment. ECF No. 250-1.

Respectfully Submitted:

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<sup>1</sup> U.S. Food & Drug Admin., *FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review*, available at: <https://tinyurl.com/mr2tbh4r>.

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